K102322

510(k) Summary for the Spine 360 Interbody Fusion System

JAN - 7 2011

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the Spine 360 Interbody Fusion System.

Date Prepared: December 2, 2010

1. **Submitter:**
Spine 360
5000 Plaza on the Lake, Suite 305
Austin, TX 78746

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** Spine 360 Interbody Fusion System
Common Name: intervertebral body fusion device
Classification Name: intervertebral body fusion device - lumbar
21 CFR section 888.3080
MAX
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**
Spine 360 Interbody Fusion System is substantially equivalent to the following devices.
   - BRANTIGAN I/F CAGE (P960025)
   - Lucent Straight Intervertebral Body Fusion Device (K072120)

4. **Description of the device:**
The SHARK implant (PLIF) consists of rectangular blocks with a tapered nose. The BULLSHARK implant (PLIF) is rectangular in shape with a conical nose. Both devices have parallel configurations of various heights.

The TIGER implant (TLIF) consists of banana shaped blocks in a parallel configuration of various heights. Large bone graft windows are located through the body of the device to allow for placement of bone graft and facilitate fusion.

The GREAT WHITE implants (ALIF) are oval shaped blocks, which are available in a two lordotic configurations (7° and 13°) of various heights. The hollow cylinders allow for placement of bone graft and facilitate fusion.

Materials:
PEEK-OPTIMA LT1 polymer (ASTM F2026 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications) and tantalum according to ASTM F560.

5. Substantial equivalence claimed to predicate devices

JAN - 7 2011

Spine 360 Cervical Interbody Fusion System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances. The table below compares the features and characteristics of the Spine 360 Cervical Interbody Fusion System to these predicate devices.

Device	Spine 360	Crystal Cervical Cage	BAK/C Vista	BRANTIGAN	Lucent
510(k) number	--	K073351	P980048 S3	P960025	K072120
Intended use	Per 888.3080	Per 888.3080	Per 888.3080	Per 888.3080	Per 888.3080
Bone graft cavity	Yes	Yes	Yes	Yes	Yes
Ridges	Yes	Yes	Yes	Yes	Yes
X-ray markers	Yes	Yes	Yes	Yes	Yes
Raw material	PEEK Optima LT1	PEEK Optima LT1	carbon-fiber reinforced PEEK-OPTIMA® LT1 polymer	70% (poly ether ketone ether ketone ketone) (PEKEKK), 30% polyacrylonitrile carbon	PEEK Optima LT1
Sterility	Provided non-sterile Steam sterilized at hospital	Provided non-sterile Steam sterilized at hospital	Provided gamma sterilized	Provided gamma sterilized	Provided non-sterile Steam sterilized at hospital

6. **Intended Use:**

The Spine 360 Lumbar Interbody Fusion System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Spine 360 Lumbar Interbody Fusion System implants are to be used with autogenous bone graft. The Spine 360 Lumbar Interbody Fusion System implants are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

7. Non-clinical Test Summary:

The following tests were conducted:

- Static and dynamic compression testing per ASTM F2077 "Test Methods for Intervertebral Body Fusion Devices"
- Subsidence per ASTM F2267 "Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression".

8. Clinical Test Summary

No clinical studies were performed

9. **Comparison of the technological characteristics of the device to predicate and legally marketed devices:**

Spine 360 Interbody Fusion System is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Spine 360
% The Orthomedix Group, Inc.
Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

JAN - 7 2011

Re: K102322
Trade/Device Name: Spine 360 Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: December 02, 2010
Received: December 07, 2010

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102322 JAN - 7 2011

Device Name: Spine 360 Lumbar Interbody Fusion System

The Spine 360 Lumbar Interbody Fusion System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Spine 360 Lumbar Interbody Fusion System implants are to be used with autogenous bone graft. The Spine 360 Lumbar Interbody Fusion System implants are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102322